

Food and Drug Administration, HHS

§ 1005.3

(1) That the manufacturer, at his expense, will refund the cost of the electronic product plus any transportation costs,

(2) Of the amount to be refunded exclusive of transportation costs,

(3) Of the method by which the manufacturer will obtain possession of the product and make the refund.

(h) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of refunds made.

§ 1004.6 Approval of plans.

If, after review of any plan submitted pursuant to this subchapter, the Secretary determines that the action to be taken by the manufacturer will expeditiously and effectively fulfill the manufacturer's obligation under §1004.1 in a manner designed to encourage the public to respond to the proposal, the Secretary will send written notice of his approval of such plan to the manufacturer. Such approval may be conditioned upon such additional terms as the Secretary deems necessary to protect the public health and safety. Any person who contests denial of a plan shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[38 FR 28629, Oct. 15, 1973, as amended at 41 FR 48269, Nov. 2, 1976; 42 FR 15676, Mar. 22, 1977]

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

Subpart A—General Provisions

Sec.

1005.1 Applicability.

1005.2 Definitions.

1005.3 Importation of noncomplying goods prohibited.

Subpart B—Inspection and Testing

1005.10 Notice of sampling.

1005.11 Payment for samples.

Subpart C—Bonding and Compliance Procedures

1005.20 Hearing.

1005.21 Application for permission to bring product into compliance.

1005.22 Granting permission to bring product into compliance.

1005.23 Bonds.

1005.24 Costs of bringing product into compliance.

1005.25 Service of process on manufacturers.

AUTHORITY: 21 U.S.C. 360ii, 360mm.

SOURCE: 38 FR 28630, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1005.1 Applicability.

(a) The provisions of §§1005.1 through 1005.24 are applicable to electronic products which are subject to the standards prescribed under this subchapter and are offered for importation into the United States.

(b) Section 1005.25 is applicable to every manufacturer of electronic products offering an electronic product for importation into the United States.

[38 FR 28630, Oct. 15, 1973, as amended at 45 FR 81739, Dec. 12, 1980]

§ 1005.2 Definitions.

As used in this part:

The term *owner* or *consignee* means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

§ 1005.3 Importation of noncomplying goods prohibited.

The importation of any electronic product for which standards have been prescribed under section 534 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360kk) shall be refused admission into the United States unless there is affixed to such product a certification in the form of a label or tag in conformity with section 534(h) of the act (21 U.S.C. 360kk(h)). Merchandise refused admission shall be destroyed or exported under regulations prescribed by the Secretary of the Treasury unless a timely and adequate petition for permission to bring the product into compliance is filed and granted under §§ 1005.21 and 1005.22.

[69 FR 11314, Mar. 10, 2004]